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REMARKS

Claims 17 and 19–36 are pending.

OATH/ DECLARATION

The Applicants may change what they regard as the invention without submitting a new oath/declaration.

The Examiner maintains that the present application claims subject matter not originally claimed or embraced in the statement of the invention and requires a new oath/declaration. Applicants respectfully traverse the Examiner's request. The fact that claims in a continuation application are directed to originally disclosed subject matter not claimed as part of the invention of a parent application does not prevent the continuation from receiving the benefit of the filing date of the parent application. MPEP at 2172.III. See also *In re Brower*, 167 USPQ 684, 687 (CCPA 1970).

As discussed below, the parent priority applications satisfy the written description requirement as regards the subject matter of the present claims. Although the original parent application did not originally claim this subject matter, the Applicants submit that they are entitled to claim properly supported subject matter at any time during the pendency of the application. Accordingly, the original oath covered the disclosed and presently claimed subject matter. For this reason, the Applicants respectfully request withdrawal of the Examiner's request for a new oath/declaration.

PRIORITY

Both the present application and the priority applications provide support for a combination comprising a catheter and a nucleic acid comprising a gene encoding p21.

Applicants' claim of priority of U. S. Serial Nos. 08/533,942, 09/031,572 and 09/426,325 stands denied. The Examiner maintains that the present application claims subject matter not originally presented in the prior applications. Specifically, the Examiner states that the specification provides no implicit or explicit support for a combination comprising a catheter and a nucleic acid comprising a gene encoding p21.

Applicants respectfully traverse the Examiner's rejection. The Examiner admits that the specification of the present application describes a method of using a catheter for administration of a vector comprising a p21 gene. If use of a catheter and a gene is described, the combination of a catheter and gene that affects that use is necessarily also described.

The disclosures in the parent applications are identical. Hence, the method and the combination are also necessarily present in the parent applications. In particular, the use of a catheter and a nucleic acid encoding p21 for site-specific instillation of cells is shown in U.S. Patent No. 5,863,904 (U. S. Serial No. 08/533,942) at column 6, lines 51-53 and column 8, lines 36-38; in U.S. Patent No. 6,057,300 (U. S. Serial No. 09/031,572) at column 6, lines 49-51 and column 8, lines 36-38; in U.S. Patent No. 6,218,372 (U. S.

Serial No. 09/426,325) at column 6, lines 49-51 and column 8, lines 55-58; as well as in the present application at page 14, lines 18-20 and page 19, lines 3-6.

The Examiner's position seems to be that the Applicants describe the *use* of the claimed combination but not the claimed combination itself and are attempting to satisfy the written description of 35 U.S.C. § 112, first paragraph, through obviousness. This is not the case because the instant application and the parent applications necessarily and explicitly must disclose and describe the claimed combination of the p21 gene with a catheter as used in the method cited by the Examiner. This is not a matter of obviousness which those of skill in the art will appreciate. The method is taught and so must be the components and steps for practicing the method.

Hence, Applicant's original parent application and all of the applications in the priority chain support and disclose a nucleic acid encoding p21 in combination with a catheter and the denial of priority should be withdrawn

35 U.S.C. §112, FIRST PARAGRAPH REJECTIONS

One skilled in the art would have understood that the Applicants were in possession of the claimed combination at the time of the filing of the application.

Claims 17 and 19-36 are rejected under 35 U.S.C. §112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants submit that while the word “combination” may not be used in the specification, one skilled in the art would have understood that the Applicants were in possession of the claimed combination at the time of the filing of the original parent application as discussed above because the disclosed method could not be practiced without using the claimed combination. This is all that is required to meet the requirements of the written description requirement. See MPEP at 2163.II.3.(a). It is not required that the specification contains an *ipsis verbis* recitation of the claims. *Id.*

Thus for the reasons discussed here and above, Applicants request withdrawal of this rejection under 35 U.S.C. §112, first paragraph.

CLAIM REJECTIONS UNDER 35 U.S.C. §102

U.S. Patent No. 5,863,904 cannot anticipate the present claims because it was not published more than one year prior to the earliest effective priority date of the present application.

Claims 17 and 19–36 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Nabel *et al.* (U.S. Patent No. 5,863,904) (“the ‘904 patent”). Applicants respectfully traverse the Examiner’s rejection. In view of the arguments made above with respect to the priority of the instant application, Applicants submit that this application is entitled to a priority date of September 26th, 1995.

Accordingly, the '904 patent, which issued on Jan 26, 1999 cannot anticipate the present claims because it was not published more than one year prior to the priority date of the present application. Applicants request that the Examiner withdraw the 35 U.S.C. §102(b) rejection of claims 17 and 19-36.

The term catheter has a well defined meaning to those skilled in the art and does not encompass either a pipette tip or an Eppendorf tube

Claims 17, 20-22, and 31 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Xiong *et al.* Nature, 366: 701-704 (1993) ("Xiong"). The Examiner interprets the term "catheter" to include tubing, such as a pipette tip or an Eppendorf tube and speculates that since Xiong describes the cloning of p21 DNA it is apparent that laboratory supplies such as pipette tips or Eppendorf tubes were used in the cloning/isolation protocol. The Examiner alleges that the present claims are anticipated at any time when p21 cDNA was present in such tubing.

Applicants respectively traverse the Examiner's rejection. Nowhere does Xiong teach, describe or suggest a combination of a p21 gene and a catheter in accordance with the invention for any use described in the present application. Applicants submit that the term catheter has a well defined meaning to those skilled in the art. This meaning does not encompass either a pipette tip or an Eppendorf tube. For example, The American Heritage Dictionary of the English Language (American Heritage Publishing Co., Inc. 1970, p. 213) defines a catheter as a "slender, flexible tube of metal, rubber,

or plastic inserted into a body channel, such as a vein, to distend or maintain an opening to an internal cavity.” Such a definition clearly does not embrace either a pipette tip or an Eppendorf tube.

Xiong fails to disclose every element of the claims and therefore cannot anticipate the claimed subject matter. Accordingly, Applicants request that the Examiner withdraw the 35 U.S.C. §102(b) rejection of claims 17 and 19-36.

CLAIM REJECTIONS UNDER 35 U.S.C. §103

The Examiner’s combination of Xiong and Nabel does not render the invention obvious.

Claims 17 and 19 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over the combination of Xiong and Nabel *et al.*, Science, 249: 1285-88 (1990) (“Nabel”). As discussed above, Xiong fails as a primary reference. The Examiner introduces Nabel for its teaching of the use of a double-balloon catheter to introduce nucleic acid molecules directly into arterial walls.

Nabel does not make up for the deficiencies of Xiong. In particular, Nabel does not teach or suggest the specific use of p21 nucleic acid for site-specifically transforming cells *in vivo*. Applicants respectfully request that the Examiner withdraw the rejection of claims under 35 U.S.C. §103(a).

Favorable consideration and allowance of this application are respectively requested for the reasons set forth in the above remarks. If, for any reason, the Examiner feels that an interview would be helpful to resolve

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any remaining issues, he is respectfully requested to contact the undersigned attorney at (312) 321-4229.

Respectfully submitted,

Dated: June 1, 2004

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THE AMERICAN HERITAGE
ONARY
OF THE ENGLISH LANGUAGE

WILLIAM MORRIS, Editor

Published by

AMERICAN HERITAGE PUBLISHING CO., INC.

and

HOUGHTON MIFFLIN COMPANY

BOSTON/NEW YORK/ATLANTA/GENEVA, ILLINOIS/DALLAS/PALO ALTO

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551 Fifth Avenue, New York, New York 10017

Third Printing

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Standard Book Numbers: 395-09064-4 (de luxe edition);
395-09065-2 (plain edges); 395-09066-0 (thumb-indexed);
395-09070-9 (school edition)

Library of Congress Catalog Card Number 76-86995

Manufactured in the United States of America

Computer-composed by Inforonics, Inc.
in Maynard, Massachusetts

cat-head (kăt'héd') *n.* A beam projecting outward from the bow of a ship, and used as a support to lift the anchor. [CAT (nautical) + HEAD.]

ca-the-dra (ka-thē'drə) *n., pl. -drae (-drē)*. 1. The official chair or throne of a bishop. 2. The office or see of a bishop. 3. The official chair of an office or position, as of a professor. [Latin, chair, from Greek *kathedra*, seat : *kata-*, down + *hedra*, seat (see *sed-* in Appendix*).]

ca-the-dral (ka-thē'drəl) *n. Abbr. cath.* 1. The principal church of a bishop's see and one that contains his official throne. 2. Any large or important church. —*adj.* 1. Of, pertaining to, or containing a bishop's official throne. 2. Relating to or issuing from a chair of office or authority; authoritative. 3. Of or pertaining to a cathedral. [Originally *cathedral church*, from Middle English *cathedral*, of a cathedra, from Old French, from Late Latin *cathedrālis*, from Latin *cathedra*, CATHEDRA.]

Cath-er (kăth'ər), *Willa Sibert*. 1876–1947. American author. **Cath-e-rine**, **Kath-e-rine** (kăth'rin, -ər-in). A feminine given name. [Middle English *Katerine*, from Old French *Caterine*, from Latin *Katerina*, *Katharina* (influenced by Greek *katharos*, pure), from Greek *Aikaterina*.]

Cath-e-rine I (kăth'rin, -ər-in). 1684?–1727. Empress of Russia (1725–27); second wife of and successor to Peter the Great. **Cath-e-rine II** (kăth'rin, -ər-in). Called "the Great." 1729–1796. Empress of Russia (1762–96).

Cath-e-rine, Mount. The English name for Jebel Katherina. **Cath-e-rine de Mé-di-cis** (kăth'rin də mēd'ə-chē, mād'ə-sēs', kăth'ə-rin). 1519–1589. Queen of France (1547–59).

Cath-e-rine of Aragon (kăth'rin, -ər-in). 1485–1536. Queen of England; first wife of Henry VIII.

Cath-e-rine of Siena (kăth'rin, -ər-in), *Saint*. 1347–1380. Italian mystic.

catherine wheel. A firework similar to a pinwheel. [After St. Catherine of Alexandria (died A.D. 307), who was condemned to be tortured on a wheel.]

cath-e-ter (kăth'ə-tər) *n. Medicine*. A slender, flexible tube of metal, rubber, or plastic inserted into a body channel, such as a vein, to distend or maintain an opening to an internal cavity. [Late Latin *catheter*, from Greek *kathētēr*, something inserted, from *kathienai*, let fall, send down : *kata-*, down + *hienai*, to send (see *ye-* in Appendix*).]

cath-e-ter-ize (kăth'ə-tə-rīz') *tr. v.* -ized, -izing, -izes. To introduce a catheter into a bodily passage. —**cath-e-ter-i-za-tion** *n.*

ca-thex-is (ka-thēk'sis) *n.* The concentration of emotional energy upon some object or idea. [New Latin, from Greek *kathexis*, a holding, retention, from *katechein*, to hold fast : *kata-*, down + *ekhein*, to have, hold (see *segh-* in Appendix*).]

Cath-leen, **Kath-leen** (kăth'lēn'). A feminine given name. [Irish, from Middle English *Catline*, from Old French *Cateline*, variant of *Caterine*, CATHIERINE.]

cath-ode (kăth'od') *n.* 1. Any negatively charged electrode, as of an electrolytic cell, storage battery, or electron tube. 2. The positively charged terminal of a primary cell or of a storage battery that is supplying current. [Greek *kathodos*, way down, descent : *kata-*, down + *hodos*, way (see *sed-* in Appendix*).] —**ca-thod'ic** (kă-thōd'ik) *adj.* —**ca-thod'i-cal-ly** *adv.*

cathode follower. A vacuum-tube amplifying circuit with input connections between the control grid and the remote end of the cathode load, output connections between terminals of the cathode load, and usually high input impedance, low output impedance, and gain less than but approaching unity.

cathode ray. 1. A stream of electrons emitted by the cathode in electrical discharge tubes. 2. An electron in such a stream.

cath-ode-ray tube (kăth'od-rā). A vacuum tube in which a hot cathode emits electrons that are accelerated as a beam through a relatively high voltage anode, further focused or deflected electrostatically or electromagnetically, and allowed to fall on a fluorescent screen.

cat-ho-lic (kăth'lik, kăth'ə-lik) *adj.* 1. Universal; general; all-inclusive. 2. Broad and comprehensive in interests, sympathies, or the like; liberal. [Old French *catholique*, from Late Latin *catholicus*, from Greek *katholikos*, from *katholou*, in general : *kata-*, according to + *holou*, neuter genitive of *holos*, whole (see *sol-* in Appendix*).] —**ca-thol'i-cal-ly** (kă-thōl'ik-lē) *adv.*

Cath-o-lic (kăth'lik, kăth'ə-lik) *adj. Abbr. C.* 1. Of or pertaining to the universal Christian church. 2. Of or pertaining to the ancient undivided Christian church. 3. a. Of or designating those churches that have claimed to be representatives of the ancient undivided church: *Roman Catholic*, *Eastern Orthodox*, *Anglican*, and *Old Catholic*. b. Of or concerning the Roman Catholic Church. 4. Pertaining to the Western Church as opposed to the Eastern Orthodox Church. —*n. Abbr. C.* A member of any Catholic church, especially Roman Catholic. **Catholic Church**, **Roman Catholic Church** (see).

Ca-thol-i-cism (ka-thōl'ə-sīz'əm) *n.* The faith, doctrine, system, and practice of a Catholic church, especially the Roman Catholic Church. See *Roman Catholicism*.

cat-ho-lic-i-ty (kăth'ə-lis'ə-tē) *n.* 1. The condition or quality of being catholic; liberality; broad-mindedness. 2. General acceptance; universality. 3. *Capital C.* Roman Catholicism.

ca-thol-i-cize (ka-thōl'ə-sīz') *v.* -cized, -cizing, -cizes. —*tr.* 1. To make catholic. 2. To convert to Catholicism. —*intr.* 1. To become catholic. 2. To be converted to Catholicism.

cat-hol-i-con (ka-thōl'ə-kōn') *n.* A universal remedy; panacea. [French, from Medieval Latin, from Greek *katholikon*, neuter of *katholikos*, CATHOLIC.]

cat-house (kăt'hous') *n., pl. -houses (-hou'zəz)*. *Slang*. A house of prostitution; a brothel.

Cat-i-line (kăt'līn'). Latin name, Lucius Sergius Catilina.

108?–62 B.C. Roman politician; conspired to assassinate the consuls; attacked and foiled by Cicero; executed.

cat-i-on (kăt'ī'ən) *n.* An ion having a positive charge and, in electrolytes, characteristically moving toward a negative electrode. Compare *anion*. [Greek *kation*, neuter of *katiōn*, present participle of *katiēnai*, to go down : *kata-*, down + *ienai*, to go (see *ei-* in Appendix*).] —**cat'i-on'ic** (-ōn'ik) *adj.*

cat-kin (kăt'kīn') *n. Botany*. A dense, often drooping flower cluster, such as that of a birch, consisting of small, scalelike flowers. Also called "ament." [Translation of obsolete Dutch *kateken*, "little cat" (the cluster resembles a kitten's tail).]

cat-like (kăt'lik') *adj.* Like a cat; stealthy; silent.

cat-ling (kăt'ling) *n.* Also **cat-lin** (kăt'lin) (for sense 2). 1. Catgut for stringing a musical instrument. 2. *Surgery*. A long amputation knife with a two-edged blade. [CAT + -LING.]

cat nap. A short nap; light sleep.

cat-nip (kăt'nīp') *n.* A hairy, aromatic plant, *Nepeta cataria*, native to Eurasia, to which cats are strongly attracted.

Ca-to (kă'tō), **Marcus Porcius**. Called "the Elder" or "the Censor." 234–149 B.C. Roman consul and censor.

Ca-to (kă'tō), **Marcus Porcius**. Surname, Uticensis. Called "the Younger." 95–46 B.C. Roman statesman; opponent of Catiline and Caesar; great-grandson of Cato the Elder.

cat-o'-nine-tails (kăt'ə-nīn'tälz') *n.* A whip consisting of nine knotted cords fastened to a handle, formerly used for flogging. [So called because it leaves marks like the scratches of a cat.]

ca-top-ric (ka-tōp'trik) *adj.* Also **ca-top-ri-cal** (-trī-kəl). Of or pertaining to mirrors and reflected images. [Greek *katoptrikos*, from *katoptron*, mirror : *kata-*, against, *cata-* + *optos*, visible (see *okw-* in Appendix*) + -TRON.] —**ca-top'rics** *n.*

cat rig. The rig of a catboat (see).

cat's cradle. A child's game in which an intricately looped string is transferred from the hands of one player to the next, resulting in a succession of different loop patterns.

cat's-eye (kăts'ī) *n.* 1. Any of various semiprecious gems displaying a band of reflected light that shifts position as the gem is turned. 2. A colored reflector attached to the back of a vehicle to indicate its presence on the road at night.

Cats-kill Mountains (kăts'kil'). A mountain range in southeastern New York. Highest elevation, Slide Mountain (4,204 feet). Also called the "Catskills."

cat's-paw (kăts'pō') *n.* Also **cats-paw**. 1. A person used by another as a dupe or tool. 2. A light breeze that ruffles small areas of a water surface. 3. *Nautical*. A hitch in the bight of a rope, on which a tackle is hooked. ["These he useth as the monkey did the cat's paw to scrape the nuts out of the fire." M. Hawke, *Killing Is Murder* (1657).]

cat-sup. Variant of *ketchup*.

cat-tail (kăt'tāl') *n.* Any of several marsh plants of the genus *Typha*; especially, *T. latifolia*, having long, straplike leaves and a dense, cylindrical head of minute brown flowers. Also called "reed mace."

cat-ta-lo. Variant of *catalo*.

Cat-te-gat. See *Kattagat*.

cat-tle (kăt'l) *pl. n.* 1. Various animals of the genus *Bos*, especially those of the domesticated species *B. taurus*, raised in many breeds for meat and dairy products. 2. *Obsolete*. Domestic animals. 3. Human beings. Used contemptuously or humorously: "*Boys and women are for the most part cattle of this color.*" (Shakespeare). [Middle English *catel*, personal property, livestock, from Old North French, from Medieval Latin *capitale*, property, from Latin, neuter of *capitālis*, chief, primary, from *caput*, head. See *kaput* in Appendix.*]

cat-tle-man (kăt'l-mən, -mān') *n., pl. -men (-mīn, -mēn')*. A man who tends or raises cattle.

cattle prod. An electrified prod designed for driving cattle. **cat-tle-ya** (kăt'lē-ə) *n.* Any orchid of the genus *Cattleya*, having showy rose-purple or white flowers. [New Latin, after William Cattley (died 1832), British patron of botany.]

Cat-ton (kăt'n), **Bruce**. Born 1899. American historian.

cat-ty (kăt'tē) *n., pl. -ties*. Also **cat-tie**. An Asian unit of weight generally equivalent to 1½ pounds avoirdupois. [Malay *kati*.]

cat-ty (kăt'tē) *adj. -tier, -tiest*. 1. Catlike; stealthy. 2. Subtly cruel or malicious; spiteful: *a catty remark*. —**cat'ti-ly** *adv.* —**cat'ti-ness** *n.*

cat-ty-cor-nered. Variant of *cater-cornered*.

cat-ty-wam-pus. Variant of *catawampus*.

Ca-tul-lus (ka-tūl'əs), **Gaius Valerius**. Roman poet of the first century B.C.

cat-walk (kăt'wōk') *n.* A narrow platform or pathway, as on the sides of a bridge.

cat whisker. A fine, pointed wire formerly used to make electrical contact with the surface of a crystal detector.

Cau-ca (kou'kä). A river of Colombia, rising in the northwest and flowing 600 miles northward to join the Magdalena.

Cau-ca-sian (kă-kăzhən, -kăzh'ən, -kăsh'ən, -kăsh'ən) *n.* 1. A native or inhabitant of the Caucasus. 2. A member of the Caucasoid ethnic division. 3. The group of languages spoken in the area of the Caucasus that are neither Indo-European nor Altaic, including Circassian and Georgian. —*adj.* Also **Cau-cas-ic** (kă-kăsh'ik). 1. Of or pertaining to the Caucasus region, its people, or their languages and culture. 2. Caucasoid. [After the CAUCASUS (from an old belief that the "Aryan" race originated there).]

Cau-ca-soid (kă-kă-soid') *adj.* 1. *Anthropology*. Of, pertaining to, or designating a major ethnic division of the human species having certain distinctive physical characteristics such as skin color varying from very light to brown, and fine hair ranging from straight to wavy or curly. This division is considered to



cathedral
Cathedral at Troyes,
France, eastern facade



cat's cradle
Eskimo woman displaying
the loop position frequently
used in cat's cradle

